ATTACHMENT 83

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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Lead Case No.: 3:21-cv-03825-AMO-LB **REPLY IN SUPPORT OF MOTION OF INTUITIVE SURGICAL, INC. TO EXCLUDE TESTIMONY OF DR. T. KIM PARNELL** Hearing To Be Renoticed Hearing Place: Courtroom 10 Judge: The Honorable Araceli Martínez-Olguín
SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff/ Counterclaim-Defendant vs. INTUITIVE SURGICAL, INC., Defendant/ Counterclaimant.	Case No.: 3:21-cv-03496-AMO-LB Hearing To Be Renoticed Hearing Place: Courtroom 10 Judge: The Honorable Araceli Martínez-Olguín

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I. INTRODUCTION

In its Motion to exclude certain testimony of plaintiffs' engineering expert, Dr. T. Kim Parnell (Hospital Dkt. No. 124; SIS Dkt. No. 120) ("Mot."),[1] Intuitive demonstrated that: (a) Dr. Parnell's opinion that the EndoWrist use counter is an "inadequate" method of ensuring patient safety does not fit with the issues in this case, is far beyond his actual knowledge, and writes off reams of hard technical data – precisely the sort of result-oriented, science-ignoring opinion that fails the *Daubert* test; (b) Dr. Parnell's opinion that the EndoWrist use counter could be redesigned is entirely speculative because he does not actually claim that such a design exists and does not offer one; (c) Dr. Parnell's assertion of the cause of failure of certain EndoWrist instruments he observed was not the product of any reliable methodology, but instead based on nothing more than a "limited inspection" of the instruments, and is therefore inadmissible; (d) Dr. Parnell's opinion that EndoWrists may be repaired like laparoscopic instruments is once again irrelevant and depends on assertions he is not qualified to make; and (e) Dr. Parnell's opinion that SIS acted "reasonably" in relying on safety assertions made by Rebotix is not based on relevant expertise or a reliable expert methodology.

Plaintiffs' opposition (Hospital Dkt. No. 162; SIS Dkt. No. 148) ("Opp.") does not satisfy their burden of showing that Dr. Parnell's opinions are admissible under Rule 702 or *Daubert*. Plaintiffs admit that some of these opinions are inadmissible, in some instances claiming Dr. Parnell is not offering them (notwithstanding the plain language of his report). In other instances, plaintiffs ignore or mischaracterize Intuitive's arguments in a futile effort to avoid them. On the handful of occasions where plaintiffs actually engage with Intuitive's arguments, their cursory analysis lacks merit. The Court should exclude Dr. Parnell's proposed testimony concerning the challenged opinions.

[1] Given the overlap in Dr. Parnell's opinions across the two cases, Intuitive filed a single motion in both cases to avoid burdening the Court with two largely identical motions. Plaintiffs likewise filed a joint opposition.

II. ARGUMENT

A. Dr. Parnell's Opinions About the "Adequacy" of the Use Counter Are Inadmissible.

Dr. Parnell's claim that the use counter is "inadequate" does not fit with the issues in these cases, depends on assumptions that are outside his qualifications, and is not based on any independent examination or testing to generate statistically significant results about how wear-and-tear on an instrument can reliably be measured and predicted. Mot. at 5-9. Plaintiffs largely ignore these arguments, opting instead to paraphrase large portions of Dr. Parnell's report. What responses plaintiffs do offer are unavailing.

First, although plaintiffs cite cases holding as much, they ignore that "expert testimony must 'fit' the question the jury must answer," a bar that "is cleared where the evidence 'logically advances a material aspect of the proposing party's case.'" *In re Roundup Prods. Liab. Litig.*, 390 F. Supp. 3d 1102, 1112 (N.D. Cal. 2018) (citations omitted). As Intuitive explained in its Motion, Dr. Parnell's opinion on the purported insufficiency of the use counter does not fit these cases because plaintiffs' claims do not rest on the proposition that EndoWrist use counters are *insufficient* for their stated purpose of providing a reasonable assurance of safety and effectiveness for the instruments. To the contrary, plaintiffs' claims rest on the proposition that the use counters are too *strict* and prevent use of the instruments when they are still safe to use. Mot. at 6. Plaintiffs' main response is to quote a portion of Dr. Howe's opinion stating that the use limits are an "essential part" of the EndoWrist specifications. Opp. at 6. That is certainly true, but it doesn't answer Intuitive's point, and plaintiffs fail to offer any substantive explanation for how Dr. Parnell's opinion on the "adequacy" of the use counter is relevant to their claims. This lack of fit is an independent basis to exclude his testimony on the topic.

Second, plaintiffs summarize Dr. Parnell's opinions in an effort to show that they do not pertain to "patient safety," since such opinions were excluded by the court in *Rebotix*. *See* Chaput Dec. Ex. 5 (Hospital Dkt. No. 124.6; SIS Dkt. No. 120.6) at 11-12. But the pertinent section of Dr. Parnell's report posits that an assertion by Dr. Howe that "the use counter … ensures that EndoWrists can be used safely" is "false." Chaput Dec. Ex. 1 (Hospital Dkt. No. 124.2; SIS Dkt. No. 120.2) ¶ 212. If Dr. Parnell's opinions do not pertain to patient safety, then they are not responsive to Dr. Howe's opinions

and are improper on that basis alone as rebuttal testimony.[2] In any event, plaintiffs' attempt to re-characterize opinions that are essentially identical to those precluded in *Rebotix* is unavailing. Dr. Parnell acknowledged in his deposition that his opinions are the same in this case as in *Rebotix*: "I believe my opinions were consistent and were the same." Chaput Dec. Ex. 6 (Hospital Dkt. No. 124.7; SIS Dkt. No. 120.7) at 31:2-32:17. And Dr. Parnell's minimal deletions in repurposing his *Rebotix* report for this case support this testimony. For example, while Dr. Parnell struck the phrase "patient safety" in a number of places, the substance of his opinions remains unchanged, and he has gained no new expertise that would now make those opinions admissible. Mot. at 7 n.9; *see Avila v. Willits Envt'l Remediation Trust*, 633 F.3d 828, 839 (9th Cir. 2011) (finding expert witness lacked "any special training or knowledge … such that he could reliably" offer his opinion).

Plaintiffs argue that Dr. Parnell's reliance on assumptions about matters that are far beyond his expertise is permissible because Intuitive can simply use cross-examination to undermine those "factual assumptions." Opp. at 7-8 (citing *In re Tesla, Inc. Sec. Litig.*, 2022 WL 7374936, at *7 (N.D. Cal. Oct. 13, 2022)). This argument requires one to accept plaintiffs' assertion that "Dr. Parnell's assumptions are based on the types of data and engineering principles that a mechanical engineer would rely upon," (*id.* at 8), but plaintiffs offer no basis for that assertion. For example if, as plaintiffs implicitly admit, Dr. Parnell lacks any understanding of the differences between various types of colectomies (*id.*), then his opinion that such differences have a material impact on the wear and tear experienced by EndoWrist instruments, and must be accounted for in designing a use counter, is entirely unsupported. Mot. at 6-7.

Third, plaintiffs offer no response to Intuitive's argument that Dr. Parnell has not himself tested EndoWrist instruments to generate statistically significant results supporting his conclusions about measuring wear-and-tear on instruments and has performed no analysis of the extensive testing data that does exist. *See id.* at 7-8. Dr. Parnell thus cannot reach an independent, data-driven assessment of the proper use limits. Instead, he is left to dismiss Intuitive's life testing as inadequate because Intuitive did

[2] As plaintiffs acknowledge, they only offer Dr. Parnell's testimony in response to opinions by Intuitive's expert Dr. Robert Howe. Opp. at 3. Dr. Parnell was not disclosed by either SIS or the Hospital plaintiffs in the opening round of expert disclosures, when parties were required to submit expert reports on issues on which they have the burden of proof.

not (he claims) test EndoWrists "to failure." Chaput Dec. Ex. 1 ¶ 250. Apart from this surface-level critique, Dr. Parnell offers no actual assessment of Intuitive's data. Mot. at 8-9; Chaput Dec. Ex. 1 ¶¶ 250-261.

B. Dr. Parnell's Speculative Assertions About an Alternative Use Counter Are Inadmissible.

In its Motion, Intuitive demonstrated that Dr. Parnell's opinion on a supposedly possible alternative design for the use counter is speculative and inadmissible. Mot. at 9-10. Plaintiffs attempt to defend this opinion by claiming that it is based on "indisputable facts" and therefore cannot be speculative.[3] Opp. at 9-10. But those "indisputable facts" are simply that Intuitive collects certain data regarding the amount of time instruments are used and some of the forces to which they are subjected during surgeries. *See* Chaput Dec. Ex. 1 ¶ 230.[4] Plaintiffs' "indisputable facts" ignore the flaw in Dr. Parnell's opinion: he makes an immense speculative leap from the existence of a few scraps of data to the feasibility of a completely new, undisclosed design for a use counter. Dr. Parnell "did not attempt to redesign [Intuitive's] device or to redesign and implement a different criteria." Chaput Dec. Ex. 6 at 153:20-154:5. And neither Dr. Parnell nor plaintiffs identify any methodology that was used to arrive at this opinion, because none exists. Despite agreeing that design of medical devices has "a lot of considerations" (Chaput Dec. Ex. 6 at 53:20-56:20), Dr. Parnell admits that he has not actually evaluated any of those considerations in opining that an alternative design of the EndoWrist use counter is feasible. Chaput Dec. Ex. 6 at 151:16-23, 153:20-154:5.

[3] Plaintiffs claim that Dr. Parnell's alternative design opinion was not addressed by the *Rebotix* court. That is incorrect. In *Rebotix*, Dr. Parnell opined that "[a] system designed to accurately track the wear that an EndoWrist experiences in surgery would take into account both the time that instrument has been used, and the complexity of the tasks that the instrument performed at minimum, in addition to potentially tracking other factors." Chaput Dec. Ex. 4 (Hospital Dkt. No. 124.5; SIS Dkt. No. 120.5) ¶ 103. That section of Dr. Parnell's report was excluded by the *Rebotix* court. Chaput Dec. Ex. 5 at 11-12.

[4] Plaintiffs attempt to bolster Dr. Parnell's deficient opinion with information he learned after submitting his reports that is nowhere referenced in his reports. *See* Opp. at 10. To the extent Dr. Parnell is allowed to testify about alternative designs at all, Intuitive will seek to exclude any such undisclosed expert opinion.

The flaw in Dr. Parnell's *ipse dixit* opinion is made plain when examining the ostensible relevance of that opinion to these cases. Plaintiffs are permitted to present evidence of "less restrictive alternatives" to achieve Intuitive's asserted justification for the use counter. *Epic Games, Inc. v. Apple, Inc.*, 2023 WL 3050076, at *24 (9th Cir. Apr. 24, 2023); *see* Pls.' Reply & Cross-Opp. Summ. J. (Hospital Dkt. No. 169) at 18 (arguing that Dr. Parnell's hypothetical alternative use counter is a less restrictive alternative). But as the Ninth Circuit recently confirmed, the test "requires a *substantially* less restrictive alternative," and the proposed alternative "must be virtually as effective in serving the defendant's procompetitive purposes without significantly increased cost." *Epic*, 2023 WL 3050076 at *24 (emphasis in original) (internal quotation marks and citations omitted). The burden of proving a substantially less restrictive alternative is on the plaintiff. *Id.* Dr. Parnell's alternative design argument falls far short of providing an alternative that could be considered under this test. Because he has not specified an actual alternative design – and instead just posits that one is theoretically *possible* – he cannot show that it would be "virtually as effective" as the existing use counter. *Id.* at *25 (affirming district court decision disregarding evidence of an alternative design when it was "not sufficiently developed" and its implementation was unclear). Further, the lack of a specific design means that it is impossible to assess whether Dr. Parnell's hypothetical use counter would serve Intuitive's purposes "without significantly increased cost." *Id.* ("Without any evidence in the record of what this [alternative design] would look like, we cannot say that it would be virtually as effective without significantly increased cost." (internal quotation marks omitted)). Dr. Parnell's opinion is therefore irrelevant as evidence of a substantially less restrictive alternative.

C. Plaintiffs Have Agreed that Dr. Parnell Will Not Offer Testimony on the Cause of Failure of EndoWrists He Observed.

Intuitive also showed that Dr. Parnell should not be permitted to testify regarding the cause of failure of EndoWrists he observed when visiting Rebotix's facility in August 2021. Mot. at 10-12. Dr. Parnell's report states that he "did not detect damage due to wear on the instrument" when examining EndoWrists at Rebotix's facility that had been deemed "Unsuitable for Repair." Chaput Dec. Ex. 1 ¶ 91. Plaintiffs now argue that this is not Dr. Parnell's opinion at all, and that "[n]o rational reader would

interpret" this statement as "an opinion on the cause of failure of those instruments." Opp. at 11. Given that Plaintiffs have conceded that Dr. Parnell will not offer opinions about the cause of failure of the EndoWrists he saw, this portion of Intuitive's motion appears to be conceded. Plaintiffs suggest that it is relevant to the "Rebotix process" that incoming instruments were screened to eliminate broken instruments. Opp. at 11. Intuitive does not disagree with that. But the *cause* of a particular EndoWrist being broken does not have any relevance to Rebotix's inspection process – all that matters is that Rebotix rejected broken instruments for its supposed "repair" process.

Curiously, Plaintiffs go on to defend the opinion that they say no "rational reader" would understand Dr. Parnell to be offering. In doing so, they mischaracterize Intuitive's argument. As Intuitive explained, the core issue with Dr. Parnell's cause-of-failure analysis is that he articulates no *methodology* that he applied to reach his conclusions, even for the small subset of instruments he actually examined, much less for the full collection as to which he was purporting to offer his causation opinion. An opinion that is not based on reliable principles and methods is not an admissible expert opinion. Fed. R. Evid. 702. Plaintiffs argue that Dr. Parnell explained the "basis" for his opinion – that only one cable in the photographed instruments broke rather than all cables at once. *See* Opp. at 11 (citing Chaput Dec. Ex. 1 ¶ 91). But as Intuitive explained, Dr. Parnell does not explain *why* that would necessarily speak to causation, and there is nothing connecting Dr. Parnell's conclusion on the cause of failure of the EndoWrists he examined ("damage from an external object or from misuse," rather than wear and tear (Chaput Dec. Ex. 1 ¶ 91)) other than "the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Dr. Parnell's failure to employ a reliable methodology in reaching his cause of failure opinion renders it inadmissible.

D. Dr. Parnell's Opinion that EndoWrists Can Be Routinely Repaired in the Same Manner as Traditional Laparoscopic Instruments Lacks a Reliable Basis.

Dr. Parnell also offers a number of opinions about how EndoWrists can be "routinely repaired" because, he says, traditional laparoscopic instruments are repaired in the same fashion. This opinion fails because it is irrelevant, Dr. Parnell is not qualified to offer it, and it is unreliable. Mot. at 12-14.

Plaintiffs initially argue that Dr. Parnell's opinions about "repair" of laparoscopic instruments are relevant because "Rebotix describes its process as a 'repair' process." Opp. at 12. This argument takes semantics to an absurd extreme. Whatever Rebotix might have chosen to *call* its process (in furtherance of its fruitless effort to convince FDA it did not need clearance), the *fact* remains that what it was doing was very different from the simple "repair" that is typically done on a laparoscopic instrument, and Dr. Parnell identified no evidence that the two are genuinely comparable. Dr. Parnell offers no comparable examples of limited-use laparoscopic instruments that are modified to extend the number of times they can be used.

Plaintiffs' Opposition and Dr. Parnell's report make clear that a "critical and fundamental part" of the Rebotix process was identifying EndoWrist instruments that were truly broken so that those instruments could be *excluded* from the Rebotix process. *See* Opp. at 11; Chaput Dec. Ex. 6 at 114:22-115:12. For example, Rebotix did not and could not replace the cables in an EndoWrist instrument, so any instrument with broken cables was not suitable to have its use counter reset by Rebotix. Chaput Dec. Ex. 1 ¶ 60 ("If any fraying or breakage is detected on even a single wire of the cable, the instrument is not considered a candidate for repair and will not be serviced."). Rebotix never claimed to be able to repair an EndoWrist that was actually broken. Further, the elements of EndoWrists that are particularly prone to failure – the unique cable-and-pulley drive system (which Rebotix could not repair) – are not even present in laparoscopic instruments. Chaput Dec. Ex. 8 (Hospital Dkt. No. 124.9; SIS Dkt. No. 120.9) ¶¶ 35-36.

Plaintiffs go on to defend Dr. Parnell's regurgitation of other witnesses' testimony by arguing that they are simply a "basis for his opinions." Opp. at 12-13. If the cited evidence were truly just a basis for an opinion, then there might be no issue. Instead, Dr. Parnell parrots testimony of other witnesses and restates their conclusions as his own. "[E]xpert witnesses may not simply repeat hearsay without bringing their expertise to bear on it." *Caldwell v. City of San Francisco*, 2021 WL 1391464, at *5 (N.D. Cal. Apr. 13, 2021) (internal quotations and citations omitted). Yet that is precisely what Dr. Parnell does. For example, Dr. Parnell claims that "[i]t is a standard practice of hospitals to repair instruments used in traditional laparoscopic surgeries," and EndoWrist "failures are easily recognized by

surgeons, and surgeons regularly and easily replace instruments when they exhibit unintuitive motion during surgery." Chaput Dec. Ex. 1 ¶¶ 35, 53. Dr. Parnell lacks any experience that would allow him to make these observations, and he applies no expertise if offering them.

The flawed nature of Dr. Parnell's factual regurgitation is laid bare by his demonstrably false claim that a "common" failure mode for "laparoscopic instruments in need of repair" is "worn or damaged cables." Chaput Dec. Ex. 1 ¶ 38. Dr. Parnell admitted in his deposition that he is unaware of any commercially-available laparoscopic instruments that even have cables. Chaput Dec. Ex. 6 at 101:9-19. It is obviously not possible for a device component that does not even exist to fail routinely. If Dr. Parnell had any real familiarity with laparoscopic instruments, he would have recognized that his regurgitation of another witness' testimony on this point was inaccurate. But he did not (*see* Chaput Dec. Ex. 7 (Hospital Dkt. No. 124.8; SIS Dkt. No. 120.8) at 18:25-21:6, 47:15-24), and his opinion on the similarities between EndoWrists and laparoscopic instruments is therefore wholly unreliable. Plaintiffs' only answer on this point in their opposition – that the fact Dr. Parnell was able to admit in his deposition that laparoscopic instruments do not have cables shows that he does know *something* about them (Opp. at 13) – hardly answers the fact that his opinion was premised on a factual assumption that was simply untrue.

The fact that Dr. Howe offers opinions comparing EndoWrists and laparoscopic instruments (Opp. at 14) does not change this conclusion. Dr. Howe is able to offer such opinions because of his extensive experience with both types of instruments. *See, e.g.*, Chaput Dec. Ex. 8 ¶ 30 ("I have had many EndoWrist instruments in my lab, which we analyzed as part of our research efforts on new surgical instrumentation."), 35 ("I have observed the use of traditional endoscopic instruments in dozens of laparoscopic and thoracoscopic surgical procedures, and my lab has analyzed their design and function as part of our own efforts to develop minimally invasive surgical instrumentation."). Dr. Parnell has no comparable experience. If plaintiffs wished to respond to these opinions, they could have hired an expert who was qualified to do so.

E. Plaintiffs Have Admitted that Dr. Parnell Should Not Opine on the Reasonableness of SIS Relying on Safety Representations Made by Rebotix.

Intuitive showed in its Motion that Dr. Parnell offered an opinion far beyond his expertise when he argued that SIS was "reasonable" to rely on Rebotix's assurances about safety testing without reviewing any safety data. Mot. at 14-15. Plaintiffs attempt to defend this opinion by arguing that it is simply responsive to one of Dr. Howe's opinions. Opp. at 15. Dr. Howe's opinion, however, is narrowly tailored to his expertise: he explains that the safety claims SIS made in communications with customers were not supported by the highly limited information SIS had been given by Rebotix. Chaput Dec. Ex. 8 ¶¶ 130-136. Dr. Parnell goes much further, opining that it was "reasonable" for SIS to rely on Rebotix's claims for various *business* reasons – opinions that plaintiffs now readily admit that "the parties' engineering experts should not be testifying about." Opp. at 15. Plaintiffs' argument attempts to set up a false equivalence that is unsupported by the experts' reports. In contrast to Dr. Howe, Dr. Parnell nowhere argues that the safety claims SIS made actually were supported by the documentation that SIS had available to it. He instead claims that SIS did nothing wrong when it took Rebotix's claims at face value. Chaput Dec. Ex. 1 ¶¶ 102-04.[5] Given that plaintiffs admit such arguments about proper business practices are the improper subject of engineering expertise, Dr. Parnell's reasonableness opinion should be excluded.

Finally, plaintiffs also claim that Dr. Parnell "is not opining on the credibility of Rebotix or SIS." This once again contradicts his report, which squarely asserts that Rebotix's representations to SIS regarding its service process were "truthful." *Id.* ¶ 104. The question of whether a party's or witness' statements are "truthful" is reserved for the jury, not an expert, and any statements about credibility should be excluded. *See, e.g.*, *United States v. Candoli*, 870 F.2d 496, 506 (9th Cir. 1989).

[5] The question of whether these claims were supported by other data that Rebotix did not disclose to SIS, Opp. at 15, is a red herring. Dr. Howe's opinion pertains to whether SIS was in possession of data supporting its safety claims. It was not.

III. CONCLUSION

For the reasons set forth above and for the reasons stated in Intuitive's Motion, the Court should exclude Dr. Parnell's opinions that:

(1) the EndoWrist use counter is "inadequate";

(2) the EndoWrist use counter could be re-designed in the manner Dr. Parnell hypothesizes;

(3) the broken EndoWrists Dr. Parnell observed at Rebotix all failed due to "damage from an external object or misuse" rather than wear-and-tear;

(4) EndoWrists can be routinely repaired like traditional laparoscopic instruments; and

(5) SIS acted "reasonably" in performing no safety evaluation and instead relying entirely on Rebotix's representations.

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